

ARQULE INC
Form 10-Q
May 12, 2008

SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-Q

**Quarterly report pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

ArQule, Inc.

Edgar Filing: ARQULE INC - Form 10-Q

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State of Incorporation)

04-3221586

(I.R.S. Employer Identification Number)

19 Presidential Way, Woburn, Massachusetts 01801

(Address of Principal Executive Offices)

(781) 994-0300

(Registrant's Telephone Number, including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

Number of shares outstanding of the registrant's Common Stock as of May 2, 2008:

Common Stock, par value \$.01

43,832,876 shares outstanding

ARQULE, INC.

QUARTER ENDED MARCH 31, 2008

TABLE OF CONTENTS

PART I - FINANCIAL INFORMATION

Item 1. Unaudited Condensed Consolidated Financial Statements

<u>Condensed Consolidated Balance Sheets (Unaudited)</u> <u>March 31, 2008 and December 31, 2007</u>	3
<u>Condensed Consolidated Statements of Operations (Unaudited)</u> <u>Three months ended March 31, 2008 and 2007</u>	4
<u>Condensed Consolidated Statements of Cash Flows (Unaudited)</u> <u>Three months ended March 31, 2008 and 2007</u>	5
<u>Notes to Unaudited Condensed Consolidated Financial Statements</u>	6

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations 13

Item 3. Quantitative and Qualitative Disclosures about Market Risk 21

Item 4. Controls and Procedures 22

PART II - OTHER INFORMATION 22

Item 1. Legal Proceedings 22

Item 1A. Risk Factors 22

Item 2. Changes in Securities and Use of Proceeds 23

Item 3. Defaults Upon Senior Securities 23

Item 4. Submission of Matters to a Vote of Security Holders 23

Item 5. Other Information 23

Item 6. Exhibits 23

SIGNATURES

EX-31 Section 302 Certification of the Principal Executive and Financial Officer

EX-32 Section 906 Certification of the Principal Executive and Financial Officer

ARQULE, INC.

CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)

Edgar Filing: ARQULE INC - Form 10-Q

	March 31, 2008	December 31, 2007
	(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 56,529	\$ 10,835
Marketable securities-short term		124,247
Prepaid expenses and other current assets	1,990	1,426
Total current assets	58,519	136,508
Marketable securities-long term	63,035	
Property and equipment, net	5,866	3,911
Other assets	1,742	1,791
Total assets	\$ 129,162	\$ 142,210
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Accounts payable and accrued expenses	\$ 14,606	\$ 14,162
Current portion of deferred revenue	10,286	9,997
Current portion of deferred gain on sale leaseback	552	552
Total current liabilities	25,444	24,711
Restructuring accrual, net of current portion	575	738
Deferred revenue, net of current portion	26,359	25,176
Deferred gain on sale leaseback, net of current portion	3,406	3,544
Total liabilities	55,784	54,169
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.01 par value; 1,000,000 shares authorized; no shares issued or outstanding		
Common stock, \$0.01 par value; 100,000,000 shares authorized; 43,772,775 and 43,761,113 shares issued and outstanding at March 31, 2008 and December 31, 2007, respectively	438	438
Additional paid-in capital	372,143	369,196
Accumulated other comprehensive loss	(3,700)	(4)
Accumulated deficit	(295,503)	(281,589)
Total stockholders' equity	73,378	88,041
Total liabilities and stockholders' equity	\$ 129,162	\$ 142,210

The accompanying notes are an integral part of these interim unaudited financial statements.

ARQULE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (Unaudited)

Edgar Filing: ARQULE INC - Form 10-Q

	THREE MONTHS ENDED MARCH 31,		
	2008		2007
	(IN THOUSANDS, EXCEPT PER SHARE DATA)		
Revenue:			
Research and development revenue	\$	3,527	\$ 1,652
Costs and expenses:			
Research and development		13,452	13,704
General and administrative		5,634	3,510
		19,086	17,214
Loss from operations		(15,559)	(15,562)
Investment income		1,645	1,058
Net loss	\$	(13,914)	\$ (14,504)
Basic and diluted net loss per share:			
Net loss per share	\$	(0.32)	\$ (0.40)
Weighted average basic and diluted common shares outstanding		43,771	35,823

The accompanying notes are an integral part of these interim unaudited financial statements.

ARQULE, INC.

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

Edgar Filing: ARQULE INC - Form 10-Q

	THREE MONTHS ENDED MARCH 31,	
	2008	2007
	(IN THOUSANDS)	
Cash flows from operating activities:		
Net loss	\$ (13,914)	\$ (14,504)
Adjustments to reconcile loss to net cash used in operating activities:		
Depreciation and amortization	370	476
Amortization of premium/discount on marketable securities	20	(40)
Amortization of deferred gain on sale leaseback	(138)	(138)
Non-cash stock compensation	2,903	1,362
Loss on disposal of property and equipment	21	121
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(564)	(1,101)
Other assets	49	201
Accounts payable and accrued expenses	444	(912)
Restructuring accrual, net of current portion	(163)	(154)
Deferred revenue	1,472	2,598
Net cash used in operating activities	(9,500)	(12,091)
Cash flows from investing activities:		
Purchases of marketable securities	(8,857)	(20,165)
Proceeds from sale or maturity of marketable securities	66,353	32,283
Additions to property and equipment	(2,433)	(188)
Proceeds from disposal of property and equipment	87	
Net cash provided by investing activities	55,150	11,930
Cash flows from financing activities:		
Proceeds from issuance of common stock	44	55
Net cash provided by financing activities	44	55
Net increase (decrease) in cash and cash equivalents	45,694	(106)
Cash and cash equivalents, beginning of period	10,835	6,242
Cash and cash equivalents, end of period	\$ 56,529	\$ 6,136

The accompanying notes are an integral part of these interim unaudited financial statements.

ARQULE, INC.

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

Edgar Filing: ARQULE INC - Form 10-Q
(IN THOUSANDS, EXCEPT SHARE AND PER SHARE DATA)

1. NATURE OF OPERATIONS AND BASIS OF PRESENTATION

Edgar Filing: ARQULE INC - Form 10-Q

We are a clinical-stage biotechnology company organized as a Delaware corporation in 1993 and engaged in the research and development of innovative cancer therapeutics. Our mission is to introduce novel products that act selectively against cancer cells, target multiple tumor types and are well tolerated by patients.

Our lead products, which are in clinical-stage testing, consist of: ARQ 197, an orally administered inhibitor of the c-Met receptor tyrosine kinase, and ARQ 501, an intravenously administered novel activator of the cell's DNA damage response mechanism mediated by the E2F-1 transcription factor. Early-stage clinical trial results, which are available for ARQ 197 and ARQ 501, have demonstrated anti-cancer activity across multiple types of tumors.

We retain full worldwide commercial rights to ARQ 197 outside of Japan and certain other Asian countries, where we have granted commercial rights to Kyowa Hakko Kogyo Co., Ltd. (Kyowa). We are developing ARQ 501 and ARQ 761 (a new chemical entity based on ARQ 501) pursuant to our collaboration with Hoffmann-La Roche (Roche). Our agreements with these partners provide for possible future milestone payments, royalties on product sales, and development funding, in addition to payments that we have already received.

We have prepared the accompanying condensed consolidated financial statements pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with generally accepted accounting principles have been condensed or omitted pursuant to these rules and regulations. These condensed consolidated financial statements should be read in conjunction with our audited financial statements and footnotes related thereto for the year ended December 31, 2007 included in our annual report on Form 10-K filed with the SEC on March 17, 2008.

The unaudited condensed consolidated financial statements include, in our opinion, all adjustments (consisting only of normal recurring adjustments) necessary to present fairly our financial position as of March 31, 2008, and the results of our operations and cash flows for the three months ended March 31, 2008 and March 31, 2007. The results of operations for such interim periods are not necessarily indicative of the results to be achieved for the full year.

2. MARKETABLE SECURITIES AND FAIR VALUE MEASUREMENTS

We account for our marketable securities in accordance with Statement of Financial Accounting Standards (SFAS) No. 115. We classify our marketable securities as available-for-sale at the time of purchase and re-evaluate such designation as of each consolidated balance sheet date. Our marketable securities are classified as cash equivalents if the original maturity, from the date of purchase, is ninety days or less and as short-term investments if the original maturity, from the date of purchase, is in excess of ninety days since we intend to convert them into cash as necessary to meet our liquidity requirements.

Our marketable securities are reported at fair value with the related unrealized gains and losses included in accumulated other comprehensive income (loss), a component of stockholders' equity, net of tax. Realized gains or losses on the sale of marketable securities are determined using the specific-identification method and were not material for the quarters ended March 31, 2008 and 2007. We evaluate our investments periodically for possible other-than-temporary impairment by reviewing factors such as the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and our ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery of market value as well as other factors relevant to the specific securities being evaluated such as agency credit ratings and the probability of collecting amounts due based on the contractual terms of the security. We record an impairment charge to the extent that the carrying value of our available for sale securities exceeds the estimated fair value of the securities and the decline in value is determined to be other-than-temporary.

Edgar Filing: ARQULE INC - Form 10-Q

We invest our available cash primarily in money market mutual funds, and U.S. federal and state agency backed certificates, including auction rate securities, that have strong credit ratings. Auction rate securities are structured with short-term interest reset dates of generally less than 90 days, but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to twenty-eight days, investors can sell or continue to hold the securities at par value. If any of our auction rate securities were to fail an auction, due to sell orders exceeding buy orders, the funds associated with a failed auction would not be accessible until a successful auction occurred, a buyer was found outside the auction process or the underlying securities matured.

In the first quarter of 2008, certain auction rate securities failed auction due to sell orders exceeding buy orders. We reviewed our portfolio at March 31, 2008, and considered other-than-temporary impairment factors, including the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and our ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery of market value, whether the security has been downgraded by a rating agency, the low probability that we will be unable to collect all amounts due according to the contractual terms of the security, to conclude whether ArQule had an other-than-temporary impairment. After this evaluation, we determined that we had a temporary impairment of \$3.7 million, which we recorded in the quarter ended March 31, 2008 within other comprehensive loss.

ArQule's marketable securities portfolio as of December 31, 2007 was \$124.2 million. The portfolio included \$92.6 million (at cost) invested in auction rate securities of which, \$67.7 million (at cost) were associated with auctions that failed subsequent to February 12, 2008. In the quarter ended March 31, 2008, ArQule was able to sell \$26.2 million (at cost) of auction rate securities that were held at December 31, 2007. ArQule's marketable securities portfolio as of March 31, 2008 was \$66.7 million (at cost) invested in auction rate securities all of which were associated with auctions that failed subsequent to February 12, 2008. Subsequent to March 31, 2008, we were notified that certain of our auction rate securities totaling \$1.0 million are planned to be called for redemption and accordingly we expect to receive payment by the end of June 2008. The funds associated with failed auctions will not be accessible until a successful auction occurs, a buyer is found outside of the auction process or the underlying securities have matured.

The following is a summary of the fair value of available-for-sale marketable securities we held at March 31, 2008 and December 31, 2007:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
March 31, 2008				
<i>Security type</i>				
Auction rate securities	\$ 66,735	\$	\$ (3,700)	\$ 63,035
Total marketable securities	\$ 66,735	\$	\$ (3,700)	\$ 63,035
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Losses	Fair Value
December 31, 2007				
<i>Security type</i>				
Time deposits	\$ 6,169	\$	\$ (1)	\$ 6,168
Corporate bonds and notes	25,190	14	(17)	25,187
Auction rate securities	92,892			92,892
Total marketable securities	\$ 124,251	\$ 14	\$ (18)	\$ 124,247

At March 31, 2008, marketable securities are carried at fair value and are classified as non current as the funds associated with failed auctions will not be needed to meet working capital needs or to fund current operations. The net unrealized losses on marketable securities at March 31, 2008 was \$3.7 million.

Edgar Filing: ARQULE INC - Form 10-Q

The following table summarizes our investments with gross unrealized losses, aggregated by investment category and length of time that individual securities have been in a continuous unrealized loss position, at March 31, 2008:

	Less than 12 Months		12 months or more		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Auction rate securities	\$ 63,035	\$ 3,700	\$ 63,035	\$ 3,700	\$ 126,070	\$ 7,400
Total temporarily impaired securities	\$ 63,035	\$ 3,700	\$ 63,035	\$ 3,700	\$ 126,070	\$ 7,400

The temporary impairment relates to auction rate securities that failed auction due to sell orders exceeding buy orders. The Company believes these auction failures are due to the lack of current liquidity in the auction rate market, rather than the quality of the underlying collateral. The underlying collateral of our auction rate securities consists primarily of student loans, the majority of which are supported by the federal government as part of the Federal Family Education Loan Program (FFELP). The credit ratings for all of our auction rate securities are AAA.

We continue to monitor the market for auction rate securities and consider its impact, if any, on the fair value of our investments. If current market conditions deteriorate further, we may be required to record additional unrealized losses in other comprehensive income. If the credit rating of the security issuers deteriorates, the anticipated recovery in market values does not occur, or we need funds from the auction rate securities to meet working capital needs or to fund current operations, we may be required to adjust the carrying value of these investments through impairment charges.

Effective January 1, 2008, we implemented SFAS No. 157, *Fair Value Measurement*, or SFAS 157, for our financial assets and liabilities that are re-measured and reported at fair value at each reporting period, and non-financial assets and liabilities that are re-measured and reported at fair value at least annually. In accordance with the provisions of Financial Accounting Standards Board (FASB) Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, we have elected to defer implementation of SFAS 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. We are evaluating the impact, if any, this Standard will have on our non-financial assets and liabilities.

The adoption of SFAS 157 for our financial assets and liabilities and non-financial assets and liabilities that are re-measured and reported at fair value at least annually did not have a material impact on our financial results.

The following table presents information about our assets that are measured at fair value on a recurring basis as of March 31, 2008, and indicates the fair value hierarchy of the valuation techniques we utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and includes situations where there is little, if any, market activity for the asset or liability:

Description	March 31, 2008	Quoted Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Cash equivalents	\$ 53,187	\$ 53,187	\$	\$

Edgar Filing: ARQULE INC - Form 10-Q

Marketable securities - long term		63,035				63,035
Total	\$	116,222	\$	53,187	\$	63,035

Our marketable securities- long term consist entirely of auction rate securities. Due to the lack of market quotes relating to our auction rate securities portfolio the fair value measurements have been estimated using an income approach model (discounted cash flow analysis) which is exclusively based on Level 3 inputs. The model considers factors that reflect assumptions market participants would use in pricing including among others, the collateralization underlying the

Edgar Filing: ARQULE INC - Form 10-Q

investments, the creditworthiness of the counterparty, the expected future cash flows, liquidity premiums, the probability of successful auctions in the future, and interest rates. The assumptions used are subject to volatility and may change as the underlying sources of these assumptions and markets conditions change.

The following table is a roll forward of the fair value of our auction rate securities, whose fair value is determined by Level 3 inputs:

Description	Amount (\$ in millions)	
Balance at December 31, 2007	\$	92.9
Total unrealized losses included in other comprehensive income		(3.7)
Settlements		(26.2)
Balance at March 31, 2008	\$	63.0

3. COMPREHENSIVE LOSS

Edgar Filing: ARQULE INC - Form 10-Q

Comprehensive loss is comprised of net loss and other comprehensive income (loss). Other comprehensive income (loss) includes unrealized gains (losses) on our available-for-sale securities that are excluded from net loss. Total comprehensive loss for the three months ended March 31, 2008 and March 31, 2007 was as follows:

	Three Months Ended March 31,		
	2008		2007
Net loss	\$	(13,914)	\$ (14,504)
Unrealized (loss) gain on marketable securities		(3,700)	79
Comprehensive loss	\$	(17,614)	\$ (14,425)

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Edgar Filing: ARQULE INC - Form 10-Q

Accounts payable and accrued expenses include the following at March 31, 2008 and December 31, 2007:

	Three Months Ended	
	March, 31, 2008	December 31, 2007
Accounts payable	\$ 2,652	\$ 548
Accrued payroll	1,136	1,954
Accrued outsourced pre-clinical and clinical fees	7,844	9,307
Accrued professional fees	452	496
Accrued restructuring-current portion	636	629
Other accrued expenses	1,886	1,228
	\$ 14,606	\$ 14,162

5. RESTRUCTURING CHARGES

Edgar Filing: ARQULE INC - Form 10-Q

In 2002, we recorded a restructuring charge associated with abandoning our facility in Redwood City, California, which was comprised of the difference between the remaining lease obligation, which runs through 2010, and our estimate of potential future sublease income. The accrual balance was adjusted in 2003 to reflect a change in estimate due to continued deterioration in the local real estate market. The accrual balance was adjusted again in 2004 as a result of us entering into a

Edgar Filing: ARQULE INC - Form 10-Q

sublease for the facility. The remaining facility-related restructuring accrual is primarily comprised of the difference between our lease obligation for this facility, which will be paid out through 2010, and the amount of sublease payments we will receive under our sublease agreement.

Activities against the restructuring accrual in the three months ended March 31, 2007 and March 31, 2008 were as follows:

	Balance as of December 31, 2006		2007 Provisions		2007 Payments		Balance as of March 31, 2007
Facility-related	\$ 2,044	\$		\$	(168)	\$	1,876

	Balance as of December 31, 2007		2008 Provisions		2008 Payments		Balance as of March 31, 2008
Facility-related	\$ 1,366	\$		\$	(155)	\$	1,211

6. NET LOSS PER SHARE

Edgar Filing: ARQULE INC - Form 10-Q

Net loss per share is computed using the weighted average number of common shares outstanding. Basic and diluted net loss per share amounts are equivalent for the periods presented as the inclusion of potential common shares in the number of shares used for the diluted computation would be anti-dilutive to loss per share. Potential common shares, the shares that would be issued upon the exercise of outstanding stock options, were 5,212,279 and 4,610,118 for the three months ended March 31, 2008 and 2007, respectively.

7. STOCK-BASED COMPENSATION AND STOCK PLANS

Edgar Filing: ARQULE INC - Form 10-Q

Effective January 1, 2006, we adopted the provisions of SFAS No.123(R), Share-Based Payment (SFAS 123 (R)), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123(R), stock-based compensation cost is measured at the grant date, based on the calculated fair value of the award, and is recognized as an expense over the employees' requisite service period (generally the vesting period of the equity grant).

We estimate the fair value of stock options using the Black-Scholes valuation model. Key input assumptions used to estimate the fair value of stock options include the exercise price of the award, expected option term, expected volatility of our stock over the option's expected term, risk-free interest rate over the option's expected term, and the expected annual dividend yield. We believe that the valuation technique and approach utilized to develop the underlying assumptions are appropriate in calculating the fair values of our stock options granted in the three months ended March 31, 2008 and March 31, 2007.

The following table presents stock-based compensation expense included in our Condensed Consolidated Statements of Operations:

	Three Months Ended			
	March 31,			
	2008		2007	
Research and development	\$	437	\$	1,020
General and administrative		2,466		342
Total stock-based compensation expense	\$	2,903	\$	1,362

In the three months ended March 31, 2008 and March 31, 2007, no stock-based compensation expense was capitalized and there were no recognized tax benefits associated with the stock-based compensation expense. Stock-based compensation expense of \$2,237, included in general and administrative in the first quarter of 2008, resulted from amendments to the former CEO's employment agreement in October 2007 and January 2008. Stock-based compensation expense of \$637,

Edgar Filing: ARQULE INC - Form 10-Q

included in research and development in the first quarter of 2007 was related to Boston Biomedical, Inc. transition costs (see Note 9 Boston Biomedical, Inc. Collaboration in this Form 10-Q).

Option activity under our stock plans for the quarter ended March 31, 2008 was as follows:

Stock Options	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2007	4,477,862	\$ 6.78
Granted	837,431	4.18
Exercised	(2,737)	4.81
Cancelled	(100,277)	6.83
Outstanding as of March 31, 2008	5,212,279	\$ 6.36
Exercisable as of March 31, 2008	2,774,806	\$ 7.08

The aggregate intrinsic value of options outstanding at March 31, 2008 was \$610, of which \$184 related to exercisable options. The weighted average fair value of options granted in the three months ended March 31, 2008 and 2007 was \$2.83 and \$3.23 per share, respectively. The intrinsic value of options exercised in the three months ended March 31, 2008 and 2007 was \$0 and \$70, respectively.

The total compensation cost not yet recognized as of March 31, 2008 related to non-vested option awards was \$6.7 million, which will be recognized over a weighted-average period of 3 years. During the three months ended March 31, 2008, there were 85,150 shares forfeited with a weighted average grant date fair value of \$3.48 per share. The weighted average remaining contractual life for options exercisable at March 31, 2008 was 4.6 years.

8. RECENT ACCOUNTING PRONOUNCEMENTS

Edgar Filing: ARQULE INC - Form 10-Q

In September 2006, the FASB issued SFAS No. 157 (SFAS 157), *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This accounting standard is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 did not have a material effect on our financial position or results of operations. In accordance with the provisions of FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, we have elected to defer implementation of SFAS 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. We are evaluating the impact, if any, this Standard will have on our non-financial assets and liabilities.

The adoption of SFAS 157 to our financial assets and liabilities and non-financial assets and liabilities that are re-measured and reported at fair value at least annually did not have a material impact on our financial results.

In February 2007, the FASB issued SFAS No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities*, which permits entities to choose to measure, on an item-by-item basis, specified financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are required to be reported in earnings at each reporting date. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The provisions of this statement are required to be applied prospectively. The Company adopted SFAS No. 159 in the first quarter of 2008. There was no significant impact to the Company's Consolidated Financial Statements from the adoption of SFAS 159.

In December 2007, the FASB issued SFAS No. 141R(SFAS 141R), *Business Combinations, a revision to SFAS No. 141, Business Combinations*. SFAS 141R provides revised guidance for recognition and measurement of identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree at fair value. The Statement also establishes disclosure requirements to enable the evaluation of the nature and financial effects of a business combination. SFAS 141R is required to be applied prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 (January 1, 2009 for

the Company). The Company is currently evaluating the potential impact, if any, of the adoption of SFAS 141R on its Consolidated Financial Statements.

9. BOSTON BIOMEDICAL, INC. COLLABORATION

Edgar Filing: ARQULE INC - Form 10-Q

In January 2007, we entered into a \$5.0 million, eight-month sponsored research agreement with the newly established Boston Biomedical, Inc. (BBI), an independent corporation led by our former chief scientific officer. Approximately 26 former employees of ArQule have joined BBI.

BBI conducts scientific research under the agreement that includes a number of *in vivo* and *in vitro* studies, reports and publications related to mechanisms of action and biomarkers for our clinical-stage products. These products include ARQ 197, ARQ 501 and ARQ 171. We retain all intellectual property and technology rights related to research conducted by BBI employees under the contract. ArQule has no equity position in BBI.

In connection with the foregoing events, on January 26, 2007, our former chief scientific officer entered into a separation agreement and general release with us and was paid a lump sum severance payment comprised of (i) one year's salary in the amount of \$321 (ii) the average of his cash bonuses over the last two years in the amount of \$110 and (iii) the amount of \$113 to which he was entitled under our Annual Incentive Program for fiscal year 2006.

In addition, he was granted an option to purchase 64,375 shares of our common stock, which is fully vested and exercisable on the date of grant and will expire on December 31, 2008. His previously vested option grants covering 216,250 shares were amended to extend the exercise period through December 31, 2007. In connection with his appointment as Chairman of our Scientific Advisory Board, he was granted an additional option to purchase 12,500 shares, which is fully vested and exercisable on the date of grant and will expire ten years after the date of grant. As a result of his separation from service, all his unvested options have lapsed.

Approximately 26 of our former employees joined BBI in January 2007 and each employee who transitioned to BBI executed and delivered a Separation Agreement and General Release. In consideration for entering into such agreement, each employee received a fully-vested option to purchase shares of our common stock with an exercise period terminating on December 31, 2008, as well as an amendment to their previously vested stock options to extend the exercise period through December 31, 2007. The total number of fully vested stock options issued to these employees was 87,500, and the total number of stock options that were amended to extend the exercise was 92,504. As a result of separation of service all unvested options of such employees have lapsed.

In the first quarter of 2007, we expensed approximately: \$431 related to lump sum cash payments under the separation and general release agreement with our former chief scientific officer, as well as certain non-cash charges for stock based compensation, including \$201 for stock options granted to him; and \$168 arising from the extension of the exercise period of his vested options. Additionally, in the first quarter of 2007, we expensed approximately \$197 for stock options granted to other employees related to their separation agreements and releases, and \$71 arising from the extension of the exercise period of their vested options.

Through December 31, 2007, in connection with the BBI sponsored research agreement, we incurred \$4,669 of research and development expense, and incurred no expense in the first quarter of 2008. Through March 31, 2008 we made payments of \$4,669 to BBI.

10. INCOME TAXES

Edgar Filing: ARQULE INC - Form 10-Q

We adopted the provisions of FASB Interpretation No. 48 (FIN 48) *Accounting for Uncertainty in Income Taxes, an interpretation of FASB Statement No. 109* (SFAS 109) on January 1, 2007. As a result of the implementation of FIN 48, we recorded no adjustment for unrecognized income tax benefits. At the adoption date of January 1, 2007 and also at March 31, 2008, we had no unrecognized tax benefits. We do not expect that the total amount of unrecognized tax benefits will significantly increase in the next twelve months.

We recognize interest and penalties related to uncertain tax positions in income tax expense. As of March 31, 2008, we had no accrued interest or penalties related to uncertain tax positions. The tax years 2003 through 2006 remain open to examination by the major taxing jurisdictions to which we are subject, which is primarily the U.S.

As of December 31, 2007, we had federal net operating losses (NOL), state NOL, and research and development credit carryforwards of approximately \$179,629, \$114,057 and \$16,038 respectively, which can be used to offset future federal and state income tax liabilities and expire at various dates through 2027. Federal net capital loss carryforwards of approximately \$5,000 can be used to offset future federal capital gains and expire at various dates through 2008. Approximately \$17,394 of our federal NOL and \$1,679 of our state NOL were generated from excess tax deductions from share-based awards, the tax benefit of which will be credited to additional paid-in-capital when the deductions reduce current taxes payable.

Utilization of NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future provided by Section 382 of the Internal Revenue Code of 1986, as amended, as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50 percentage points over a three-year period. Since the Company's formation, the Company has raised capital through the issuance of capital stock on several occasions which, combined with the purchasing shareholders' subsequent disposition of those shares, may have resulted in a change of control, as defined by Section 382, or could result in a change of control in the future upon subsequent disposition. The Company has not currently completed a study to assess whether a change of control has occurred or whether there have been multiple changes of control since the Company's formation due to the significant complexity and cost associated with such study and that there could be additional changes in control in the future. If we have experienced a change of control at any time since Company formation, utilization of our NOL or R&D credit carryforwards would be subject to an annual limitation under Section 382. Any limitation may result in expiration of a portion of the NOL or R&D credit carryforwards before utilization. Further, until a study is completed and any limitation known, no amounts are being presented as an uncertain tax position under FIN 48.

11. SUBSEQUENT EVENT

On May 8, 2008, the Company entered into a \$15 million standard margin loan agreement which is secured by the auction rate securities held by the Company. The margin loan currently bears interest at LIBOR plus 25 basis points. As of May 12, 2008, there was no outstanding amount under this margin loan.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

OVERVIEW

Edgar Filing: ARQULE INC - Form 10-Q

We are a clinical-stage biotechnology company organized as a Delaware corporation in 1993 and engaged in the research and development of innovative cancer therapeutics. Our mission is to introduce novel products that act selectively against cancer cells, target multiple tumor types and are well tolerated by patients. We believe our clinical stage products represent potential best-in-class or first-in-class small molecule candidates based on highly differentiated mechanisms of action.

Our lead products, which are in clinical-stage testing, consist of: ARQ 197, an orally administered inhibitor of the c-Met receptor tyrosine kinase, and ARQ 501, an intravenously administered novel activator of the cell's DNA damage response mechanism mediated by the E2F-1 transcription factor. Early-stage clinical trial results, which are available for ARQ 197 and ARQ 501, have demonstrated anti-cancer activity across multiple types of tumors.

We retain full worldwide commercial rights to ARQ 197 outside of Japan and certain other Asian countries, where we have granted commercial rights to Kyowa Hakko Kogyo Co., Ltd. (Kyowa). We are developing ARQ 501 and ARQ 761 (a new chemical entity based on ARQ 501) pursuant to our collaboration with Hoffmann-La Roche (Roche). Our agreements with these partners provide for possible future milestone payments, royalties on product sales, and development funding, in addition to payments that we have already received.

Our pre-clinical programs are directed toward molecular targets that we believe play critical roles in the development of human cancers. The targets, mechanisms of action and chemistry related to compounds generated from these

programs differ, offering the potential for multiple therapeutic opportunities. The most advanced of these programs are focused on the development of inhibitors of the Eg5 kinesin spindle protein and the B-RAF kinase. Toxicology testing is planned to begin in 2008 with a product candidate from the Eg5 program. Additional molecular targets being explored in other pre-clinical programs.

Our products and research programs are based on our understanding of biological processes that lead to the proliferation and metastasis of cancer cells, combined with our ability to generate product candidates possessing certain pre-selected, drug-like properties and designed to act with specificity against cancer cells. We believe that these qualities, when present from the earliest stages of product development, increase the likelihood of producing safe, effective and marketable drugs. We believe that our combined expertise in chemistry and cancer biology differentiates us from other companies with a similar stage of evolution.

We will be focusing and advancing a significant portion of our drug discovery efforts based on our newly acquired understanding of the way ARQ 197 binds to c-Met. Insights into this novel binding mechanism form the basis of a discovery platform that we plan to leverage to generate a new type of selective kinase inhibitors. These compounds will be designed to inhibit a variety of kinases potently, selectively and without competing with ATP (adenosine triphosphate, an energy source for cells). We are currently assessing the potential of multiple kinases as targets for this drug discovery platform, and we are seeking to generate and validate compounds that inhibit these kinase targets with mechanisms similar to that of ARQ 197.

We have incurred a cumulative net loss of \$296 million from inception through March 31, 2008. We expect research and development costs to increase throughout 2008, due primarily to clinical testing of ARQ 197. We recorded a net loss for 2006 and 2007, and expect a net loss for 2008. Our revenue consists primarily of development funding from our alliances with Kyowa and Roche. Revenue and expenses fluctuate from quarter to quarter based upon a number of factors, notably: the timing and extent of our cancer related research and development activities together with the length and outcome of our clinical trials.

On April 2, 2004, we announced an alliance with Roche to discover and develop drug candidates targeting the E2F biological pathway, including ARQ 501. Pursuant to terms of the agreement, Roche obtained an option to license our E2F program in the field of cancer therapy. Roche provided immediate research funding of \$15 million, and is providing financial support for ongoing research and development. Under this alliance, we are responsible for advancing drug candidates from early stage development to Phase 2 trials. Roche may opt to license worldwide rights for the development and commercialization of products resulting from this collaboration by paying an option fee. Assuming the successful development and commercialization of a compound under the program, we could receive up to \$276 million in pre-determined payments, plus royalties based on net sales. Additionally, we have the option to co-promote products in the U.S. Financial support under our 2004 agreement with Roche terminated in the quarter ended March 31, 2008. Roche's option under this agreement continues through December 31, 2008, and Roche has the right to extend the option period through December 31, 2009 in exchange for financial support of further program deliverables.

On April 27, 2007, we entered into an exclusive license agreement with Kyowa to develop and commercialize ARQ 197, a small molecule, selective inhibitor of the c-Met receptor tyrosine kinase, in Japan and parts of Asia. A \$3 million portion of an upfront licensing fee was received by the Company under this agreement in the first quarter of 2007 and an additional \$27 million in upfront licensing fees was received on May 7, 2007. The agreement includes \$123 million in upfront and potential development milestone payments from Kyowa to ArQule, including the \$30 million cash upfront licensing payments. In the first quarter of 2008, we received a \$3 million development milestone payment from Kyowa. In addition, the agreement includes sales milestone payments. Upon commercialization, ArQule will receive double-digit royalties from Kyowa on net sales of ARQ 197. Kyowa will be responsible for all clinical development costs and commercialization of the compound in certain Asian countries, consisting of Japan, China (including Hong Kong), South Korea and Taiwan.

Revenue and expenses fluctuate from quarter-to-quarter based upon a number of factors, notably the timing and extent of our cancer-related research and development activities together with the duration and outcomes of our clinical trials.

LIQUIDITY AND CAPITAL RESOURCES

Edgar Filing: ARQULE INC - Form 10-Q

	March 31, 2008	December 31, 2007	Increase (decrease)	
		(in millions)	\$	%
Cash, cash equivalents and marketable securities-short term	\$ 56.5	\$ 135.1	\$ (78.6)	(58)%
Marketable securities- long term	63.0		63.0	100%

	Q1 2008	Q1 2007	Increase (decrease)	
		(in millions)		
Cash flow from:				
Operating activities	\$ (9.5)	\$ (12.1)		\$ 2.6
Investing activities	55.2	11.9		43.3
Financing activities	0.1	0.1		

Cash flow from operating activities. Our uses of cash for operating activities have primarily consisted of salaries and wages for our employees, facility and facility-related costs for our offices and laboratories, fees paid in connection with preclinical and clinical studies, laboratory supplies and materials, and professional fees. The sources of our cash flow from operating activities have consisted primarily of payments from our collaborators for services performed or upfront payments for future services. For the three months ended March 31, 2008, our net use of cash was primarily driven by the difference between cash receipts from our collaborators, and payments for operating expenses which resulted in a net cash outflow of \$9.5 million.

Cash flow from investing activities. Our net cash provided by investing activities of \$55.2 million in 2008 was primarily comprised of net sales of marketable securities of \$57.5 million, partially offset by acquisitions of fixed assets of \$2.4 million. The composition and mix of cash, cash equivalents and marketable securities may change frequently as a result of the Company's constant evaluation of conditions in financial markets, the maturity of specific investments, and our near term liquidity needs.

Our cash equivalents and marketable securities include money market funds and US federal and state agency backed certificates, including auction rate securities that have strong credit ratings.

Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in the market value due to changes in interest rates.

Auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than ninety days but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to twenty-eight days, investors can sell or continue to hold the securities at par. These securities are subject to fluctuations in fair value depending on the supply and demand at each auction. In the first quarter of 2008, certain auction rate securities failed auction due to sell orders exceeding buy orders. We reviewed our portfolio at March 31, 2008, and considered other-than-temporary impairment factors, including the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and our ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery of market value, whether the security has been downgraded by a rating agency, the low probability that we will be unable to collect all amounts due according to the contractual terms of the security, to conclude whether ArQule had an other-than-temporary impairment. After this evaluation, we determined that we had a temporary impairment of \$3.7 million, which we recorded in the quarter ended March 31, 2008 within other comprehensive loss.

Edgar Filing: ARQULE INC - Form 10-Q

ArQule's marketable securities portfolio as of December 31, 2007 was \$124.2 million. The portfolio included \$92.6 million (at cost) invested in auction rate securities of which, \$67.7 million (at cost) were associated with auctions that failed subsequent to February 12, 2008. In the quarter ended March 31, 2008, ArQule was able to sell \$26.2 million (at cost) of auction rate securities that were held at December 31, 2007. ArQule's marketable securities portfolio as of March 31, 2008 was \$66.7 million (at cost) invested in auction rate securities all of which were associated with auctions that failed

Edgar Filing: ARQULE INC - Form 10-Q

subsequent to February 12, 2008. Subsequent to March 31, 2008, we were notified that certain of our auction rate securities totaling \$1.0 million were planned to be called for redemption and accordingly we expect to receive payment by the end of May 2008. The funds associated with failed auctions will not be accessible until a successful auction occurs, a buyer is found outside of the auction process or the underlying securities have matured.

Given the current liquidity constraints in the auction rate securities market, and depending on decisions we may make regarding our clinical trials, we expect that our available cash and cash equivalents, together with cash from operations and investment income, will be sufficient to finance our working capital and capital requirements at least through the first quarter of 2009. Pending increased stability and liquidity in the auction rate securities market, we believe we can fund our operations through the end of 2009.

Cash flow from financing activities. Our net cash provided by financing activities of \$0.1 million in the quarters ended March 31, 2008 and 2007 was from the issuance of common stock associated with the exercise of outstanding stock options.

On May 8, 2008, the Company entered into a \$15 million standard margin loan agreement which is secured by the auction rate securities held by the Company. The margin loan currently bears interest at LIBOR plus 25 basis points. As of May 12, 2008, there was no outstanding amount under this margin loan.

Our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, our ability to enter into additional corporate collaborations and the terms of such collaborations, results of research and development, unanticipated required capital expenditures, competitive and technological advances, acquisitions, financial market conditions and other factors. We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product. It is likely we will need to raise additional capital or incur indebtedness to continue to fund our operations in the future. Our ability to raise additional funds will depend on financial, economic and market conditions and other factors, many of which are beyond our control. There can be no assurance that sufficient funds will be available to us when required, on satisfactory terms, or at all. If necessary funds are not available, we may have to delay, reduce the scope of, or eliminate some of our development programs, potentially delaying the time to market for any of our product candidates.

Our contractual obligations were comprised of the following as of March 31, 2008 (in thousands):

Contractual Obligations	Total	Payment due by period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease obligations	\$ 24,772	\$ 3,886	\$ 7,343	\$ 6,984	\$ 6,559
Purchase obligations	8,215	8,215			
Total	\$ 32,987	\$ 12,101	\$ 7,343	\$ 6,984	\$ 6,559

Included in the total minimum payments for operating leases is approximately \$1.2 million related to abandoned real estate in California, net of contractual sublease income. This net amount has been accrued as a liability as a part of the Company's restructuring charge in 2002 and subsequently adjusted in 2003 and 2004 (see Note 5 Restructuring Charges to the Condensed Consolidated Financial Statements in this Form 10-Q). Purchase obligations are comprised primarily of outsourced pre-clinical and clinical trial expenses and payments to license certain intellectual property to support the Company's research efforts.

CRITICAL ACCOUNTING POLICIES AND ESTIMATES

A critical accounting policy is one which is both important to the portrayal of the Company's financial condition and results and requires management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For additional information, please see the discussion of our significant accounting policies in Note 3 to the Consolidated Financial Statements included in our Annual Report on Form 10-K filed with the SEC on March 17, 2008.

Research and Development Revenue Recognition

Pursuant to the terms of the Roche agreement, Roche obtained an option to license ArQule's E2F program in the field of cancer therapy in 2004. Roche provided immediate research funding of \$15 million, and financial support for ongoing research and development. ArQule is responsible for advancing drug candidates from early stage development into

Phase 2 trials. Roche may opt to license worldwide rights for the development and commercialization of products resulting from this collaboration by paying an option fee. Assuming the successful development and commercialization of a compound under the program, ArQule could receive up to \$276 million in pre-determined milestone payments, plus royalties based on net sales. ArQule considers the development portion of the arrangement to be a single unit of accounting under Emerging Issues Task Force 00-21 for purposes of revenue recognition, and recognizes the initial and ongoing development payments as research and development revenue over the maximum estimated development period. We estimate the maximum development period could extend until December 2009. This period may ultimately be shorter depending upon the outcome of the development work, resulting in accelerated recognition of the development revenue. Milestone and royalty payments will be recognized as revenue when earned. The cost associated with satisfying the Roche contract is included in research and development expense in the Consolidated Statement of Operations. Financial support under our 2004 agreement with Roche terminated in the quarter ended March 31, 2008. Roche's option under this agreement continues through December 31, 2008, and Roche has the right to extend the option period through December 31, 2009 in exchange for financial support of further program deliverables.

On April 27, 2007, we entered into an exclusive license agreement with Kyowa to develop and commercialize ARQ 197, a small molecule, selective inhibitor of the c-Met receptor tyrosine kinase, in Japan and parts of Asia. A \$3 million portion of an upfront licensing fee was received by the Company under this agreement in the first quarter of 2007 and an additional \$27 million in upfront licensing fees was received on May 7, 2007. The agreement includes \$123 million in upfront and potential development milestone payments from Kyowa to ArQule, including the \$30 million cash upfront licensing payments. In the first quarter of 2008 we received a \$3 million milestone payment from Kyowa. In addition, the agreement includes sales milestone payments. Upon commercialization, ArQule will receive double-digit royalties from Kyowa on net sales of ARQ 197. Kyowa will be responsible for all clinical development costs and commercialization of the compound in certain Asian countries, consisting of Japan, China (including Hong Kong), South Korea and Taiwan.

Pursuant to the Kyowa agreement, the initial license fee and any subsequent milestone payments, once earned, will be recognized as research and development revenue using the contingency-adjusted performance model. Under this model, when payments are earned, revenue is immediately recognized on a pro-rata basis in the period we achieve the milestone based on the time elapsed from inception of the Kyowa agreement to the time the milestone is earned over the estimated duration of the development period under the agreement. Thereafter, the remaining portion of the milestone payment is recognized on a straight-line basis over the remaining estimated development period under the agreement. We currently estimate the development period to be through April 2016. This period may ultimately be shorter or longer depending upon the outcome of the development work, resulting in accelerated or deferred recognition of the development revenue. Royalty payments will be recognized as revenue when earned. The cost associated with satisfying the Kyowa contract is included in research and development expense in the Consolidated Statement of Operations.

RESULTS OF OPERATIONS

Edgar Filing: ARQULE INC - Form 10-Q

The following are the results of operations for the three months ended March 31, 2008 and 2007:

Revenue

Edgar Filing: ARQULE INC - Form 10-Q

	2008		2007		Increase (decrease)		
	(in millions)				\$	%	
<i>For the three months ended March 31:</i>							
Research and development revenue	\$	3.5	\$	1.7	\$	1.8	113%

The first quarter of 2008 as compared to the first quarter of 2007: Research and development revenue is comprised of revenue from the Roche alliance agreement and from the Kyowa license agreement. The quarterly increase is primarily due to revenue from Kyowa.

Research and development

Edgar Filing: ARQULE INC - Form 10-Q

	2008		2007		Increase (decrease)		
	(in millions)				\$	%	
<i>For the three months ended March 31:</i>							
Research and development	\$	13.5	\$	13.7	\$	(0.2)	(2)%

Overview

Edgar Filing: ARQULE INC - Form 10-Q

Our research and development expense consists primarily of salaries and related expenses for personnel, costs of contract manufacturing services, costs of facilities and equipment, fees paid to professional service providers in conjunction with our clinical trials, fees paid to research organizations in conjunction with pre-clinical animal studies, costs of materials used in research and development, consulting, license, and sponsored research fees paid to third parties and depreciation of associated laboratory equipment. We expect our research and development expense to increase as we continue to develop our portfolio of oncology programs.

We have not accumulated and tracked our internal historical research and development costs or our personnel and personnel-related costs on a program-by-program basis. Our employee and infrastructure resources are allocated across several projects, and many of our costs are directed to broadly applicable research endeavors. As a result, we cannot state the costs incurred for each of our oncology programs on a program-by-program basis, or the cost to support our alliance agreement with Roche. The expenses incurred by us to third parties for pre-clinical and clinical trials in the first quarter 2008 and since inception of each program were as follows (in thousands):

Oncology program	Current status	Three Months Ended March 31, 2008	Program-to-date
E2F modulation ARQ 501	Phase 2	\$ 985	\$ 28,372
E2F modulation ARQ 171	Discontinued	85	5,347
c-Met program ARQ 197	Phase 2	4,361	23,501

Our future research and development expenses in support of our current and future oncology programs will be subject to numerous uncertainties in timing and cost to completion. We test potential products in numerous pre-clinical studies for safety, toxicology, and efficacy. We may conduct multiple clinical trials for each product. As we obtain results from trials, we may elect to discontinue or delay clinical trials for certain products in order to focus our resources on more promising products. Completion of clinical trials may take several years or more, but the length of time generally varies substantially according to the type, complexity, novelty, and intended use of a product. It is not unusual for the pre-clinical and clinical development of these types of products to each take nine years or more, and for total development costs to exceed \$500 million for each product.

We estimate that clinical trials of the type generally needed to secure new drug approval are typically completed over the following timelines:

Clinical Phase	Estimated Completion Period
Phase 1	1-2 years
Phase 2	2-3 years
Phase 3	2-4 years

The duration and the cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others, the following:

- the number of clinical sites included in the trials;

- the length of time required to enroll suitable patients;

- the number of patients that ultimately participate in the trials;
- the duration of patient follow-up to ensure the absence of long-term product-related adverse events; and

- the efficacy and safety profile of the product.

An element of our business strategy is to pursue the research and development of a broad pipeline of products. This is intended to allow us to diversify the risks associated with our research and development expenditures. As a result, we believe our future capital requirements and future financial success are not substantially dependent on any one product. To the extent we are unable to maintain a broad pipeline of products, our dependence on the success of one or a few products increases.

Our strategy includes entering into alliance arrangements with third parties to participate in the development and commercialization of our products, such as our collaboration agreement with Roche and the license agreement with Kyowa. In the event that third parties have control over the clinical trial process for a product, the estimated completion date would largely be under control of that third party rather than under our control. We cannot forecast with any degree of certainty whether our products will be subject to future collaborative arrangements or how such arrangements would affect our development plans or capital requirements.

As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our oncology programs or when and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete our oncology programs in a timely manner or our failure to enter into appropriate collaborative agreements could significantly increase our capital requirements and could adversely impact our liquidity. These uncertainties could force us to seek additional, external sources of financing from time-to-time in order to continue with our product development strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

The first quarter of 2008 as compared to the first quarter of 2007: The decrease in research and development expense in the first quarter of 2008 is primarily due to a \$0.2 million decrease in outsourced pre-clinical, clinical and manufacturing required principally for clinical trials with ARQ 197, ARQ 501 and ARQ 171. At March 31, 2008, we had 78 employees dedicated to our research and development program, up from 65 employees at March 31, 2007.

General and administrative

Edgar Filing: ARQULE INC - Form 10-Q

	2008		2007		Increase (decrease)	
	(in millions)				\$	%
<i>For the three months ended March 31:</i>						
General and administrative	\$	5.6	\$	3.5	2.1	61%

The first quarter of 2008 as compared to the first quarter of 2007: General and administrative expense increased in 2008 primarily due to a \$2.2 million increase in stock based compensation expense resulting from amendments to the former CEO's employment agreement in October 2007 and January 2008. General and administrative headcount was 34 at March 31, 2008 and 2007.

Investment income

Edgar Filing: ARQULE INC - Form 10-Q

	2008		2007		Increase (decrease)		
	(in millions)				\$	%	
<i>For the three months ended March 31:</i>							
Investment income	\$	1.6	\$	1.1	\$	0.5	55%

The first quarter of 2008 as compared to the first quarter of 2007: Investment income is derived from our portfolio of cash, and marketable securities. Investment income increased year-to-year due to the increased average portfolio balance.

RECENT ACCOUNTING PRONOUNCEMENTS

Edgar Filing: ARQULE INC - Form 10-Q

In September 2006, the FASB issued Statement of Financial Accounting Standards No. 157 (SFAS 157), *Fair Value Measurements*. SFAS 157 defines fair value, establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. This accounting standard is effective for fiscal

years beginning after November 15, 2007. The adoption of SFAS 157 is not anticipated to have a material effect on our financial position or results of operations. . In accordance with the provisions of FASB Staff Position No. FAS 157-2, *Effective Date of FASB Statement No. 157*, we have elected to defer implementation of SFAS 157 as it relates to our non-financial assets and non-financial liabilities that are recognized and disclosed at fair value in the financial statements on a nonrecurring basis until January 1, 2009. We are evaluating the impact, if any, this Standard will have on our non-financial assets and liabilities. The adoption of SFAS 157 to our financial assets and liabilities and non-financial assets and liabilities that are re-measured and reported at fair value at least annually did not have a material impact on our financial results.

In February 2007, the FASB issued SFAS No. 159 (SFAS 159), *The Fair Value Option for Financial Assets and Financial Liabilities*, which permits entities to choose to measure, on an item-by-item basis, specified financial instruments and certain other items at fair value. Unrealized gains and losses on items for which the fair value option has been elected are required to be reported in earnings at each reporting date. SFAS 159 is effective for fiscal years beginning after November 15, 2007. The provisions of this statement are required to be applied prospectively. The Company adopted SFAS No. 159 in the first quarter of 2008. There was no significant impact to the Company's Consolidated Financial Statements from the adoption of SFAS 159.

In December 2007, the FASB issued SFAS No. 141R(SFAS 141R), *Business Combinations, a revision to SFAS No. 141, Business Combinations*. SFAS 141R provides revised guidance for recognition and measurement of identifiable assets and goodwill acquired, liabilities assumed, and any noncontrolling interest in the acquiree at fair value. The Statement also establishes disclosure requirements to enable the evaluation of the nature and financial effects of a business combination. SFAS 141R is required to be applied prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008 (January 1, 2009 for the Company). The Company is currently evaluating the potential impact, if any, of the adoption of SFAS 141R on its Consolidated Financial Statements.

FORWARD LOOKING STATEMENTS

Edgar Filing: ARQULE INC - Form 10-Q

In addition to historical information, this report contains forward-looking statements. You can identify these forward-looking statements by their use of words such as anticipate, assume, believe, estimate, expect, forecast, intend, may, plan, project, target, will and other similar meaning. You also can identify them by the fact that they do not relate strictly to historical or current facts. All statements which address operating performance, events or developments that the Company expects or anticipates will occur in the future, such as projections about its future results of operations, its financial condition, research, development and commercialization of its products and anticipated trends in its business are forward-looking statements.

In this report we make forward-looking statements regarding our drug development pipeline and our clinical trials involving ARQ 501, ARQ 761 and ARQ 197. Additional forward-looking statements relate to our agreement with Kyowa, including potential future milestones and royalty payments that could result from the future development of ARQ 197, and to our agreement with Roche, whose option to our E2F-1 program continues through December 31, 2008, with the right to extend the option period through December 31, 2009 in exchange for financial support of further deliverables.

Drug development involves a high degree of risk. Only a small number of research and development programs result in the commercialization of a product. For example, pre-clinical efforts associated with our product pipeline may fail or prove disappointing because our technology platform did not produce candidates with the desired characteristics. Animal xenograft pre-clinical studies may be unrepresentative of human response. Positive information about early stage clinical trial results will not ensure that later stage or larger scale clinical trials will be successful.

Furthermore, our drugs may not demonstrate promising therapeutic effects; in addition, they may not demonstrate appropriate safety profiles in ongoing or later stage or larger scale clinical trials as a result of known or as yet unidentified side effects. The results achieved in later stage trials may not be sufficient to meet applicable regulatory standards. Problems or delays may arise during clinical trials or in the course of developing, testing or manufacturing our drugs that could lead us or our partner to discontinue development.

Even if later stage clinical trials are successful, the risk exists that unexpected concerns may arise from analysis of data or from additional data or that obstacles may arise or issues be identified in connection with review of clinical data with regulatory authorities or that regulatory authorities may disagree with the Company's view of the data or require additional data or information or additional studies. Also, the planned timing of initiation of clinical trials and the duration and conclusion of such trials for our drugs are subject to the ability of the company to enroll patients, enter into agreements with clinical trial sites and investigators, and other technical hurdles and issues that may not be resolved.

We also make forward-looking statements regarding the adequacy of our financial resources. Our capital resources may not be adequate because our cash requirements may vary materially from those now planned depending upon the results of our drug discovery and development strategies, the outcomes of our clinical trials, our ability to enter into additional corporate collaborations in the future and the terms of such collaborations, results of research and development, the need for currently unanticipated capital expenditures, competitive and technological advances, acquisitions, financial market conditions and other factors. Additionally, our corporate collaborators may terminate their agreements with us, thereby eliminating that source of funding, because we may fail to satisfy the prescribed terms of the collaborations or for other reasons.

We cannot guarantee that we will be able to develop any of our drug candidates into a commercial product generating revenues. If we experience increased losses, we may have to seek additional financing from public and private sales of our securities, including equity securities. There can be no assurance that additional funding will be available when needed or on acceptable terms.

The factors, risks and uncertainties referred to above and others are more fully described under the heading "Risk Factors" in our Annual Report on Form 10-K for the fiscal year ended December 31, 2007 filed with the SEC on March 17, 2008, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. The forward-looking statements contained herein represent the judgment of the Company as of the date of this report. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise, except to the extent required by law.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Edgar Filing: ARQULE INC - Form 10-Q

We own financial instruments that are sensitive to market risk as part of our investment portfolio. We have implemented policies regarding the amount and credit ratings of investments. Our investment portfolio is used to preserve our capital until it is used to fund operations, including our research and development activities. None of these market-risk sensitive instruments are held for trading purposes. Our investments are evaluated quarterly to determine the fair value of the portfolio.

Our cash and marketable securities include money market funds and US federal and state agency backed certificates, including auction rate securities that have strong credit ratings.

Our cash equivalents and our portfolio of marketable securities are subject to market risk due to changes in interest rates. Fixed rate interest securities may have their market value adversely impacted due to a rise in interest rates, while floating rate securities may produce less income than expected if interest rates fall. Due in part to these factors, our future investment income may fall short of expectation due to changes in interest rates or we may suffer losses in principal if we are forced to sell securities that decline in the market value due to changes in interest rates.

Auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than ninety days but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to twenty-eight days, investors can sell or continue to hold the securities at par. These securities are subject to fluctuations in fair value depending on the supply and demand at each auction. In the first quarter of 2008, certain auction rate securities failed auction due to sell orders exceeding buy orders. We reviewed our portfolio at March 31, 2008, and considered other-than-temporary impairment factors, including the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and our ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery of market value, whether the security has been downgraded by a rating agency, the low probability that we will be unable to collect all amounts due according to the contractual terms of the security, to conclude whether ArQule had an other-than-temporary impairment. After this evaluation, we determined that we

had a temporary impairment of \$3.7 million, which we recorded in the quarter ended March 31, 2008 within other comprehensive loss.

ArQule's marketable securities portfolio as of December 31, 2007 was \$124.2 million. The portfolio included \$92.6 million (at cost) invested in auction rate securities of which, \$67.7 million (at cost) were associated with auctions that failed subsequent to February 12, 2008. In the quarter ended March 31, 2008, ArQule was able to sell \$26.2 million (at cost) of auction rate securities that were held at December 31, 2007. ArQule's marketable securities portfolio as of March 31, 2008 was \$66.7 million (at cost) invested in auction rate securities all of which were associated with auctions that failed subsequent to February 12, 2008. Subsequent to March 31, 2008, we were notified that certain of our auction rate securities totaling \$1.0 million are planned to be called for redemption and accordingly we expect to receive payment by the end of May 2008. The funds associated with failed auctions will not be accessible until a successful auction occurs, a buyer is found outside of the auction process or the underlying securities have matured.

At March 31, 2008, marketable securities are carried at fair value and are classified as non current as the funds associated with failed auctions will not be needed to meet working capital needs or to fund current operations. The net unrealized losses on marketable securities at March 31, 2008 was \$3.7 million.

The carrying amounts reflected in the Condensed Consolidated Balance Sheet of cash and cash equivalents, and trade payables approximate fair value at March 31, 2008 due to the short-term maturities of these instruments.

ITEM 4. CONTROLS AND PROCEDURES

Edgar Filing: ARQULE INC - Form 10-Q

Our management, with the participation of our President and Chief Operating Officer (Principal Executive and Financial Officer), evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2008. The term disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (Exchange Act), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and financial officer, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2008, our President and Chief Operating Officer (Principal Executive and Financial Officer) concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

There have been no changes in the Company's internal control over financial reporting during the most recently completed fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS. None.

ITEM 1A. RISK FACTORS. For information regarding factors that could affect the Company's results of operations, financial condition and liquidity, see the risk factors discussion provided under "Risk Factors" in Item 1A of ArQule's Annual Report on Form 10-K for the year ended December 31, 2007 filed with the SEC on March 17, 2008, as updated from time to time in our subsequent Quarterly Reports on Form 10-Q and Current Reports on Form 8-K. See also, "Forward-Looking Statements" included in this Quarterly Report on Form 10-Q.

The following risk factor is the only material change to the risk factors included in our Form 10-K for the year ended December 31, 2007.

Funds associated with certain of our auction rate securities may not be accessible for an undetermined period of time and our auction rate securities may experience an other than temporary decline in value, which would adversely affect our statement of operations.

Our marketable securities portfolio includes auction rate securities that are structured with short-term interest rate reset dates of generally less than ninety days, but with contractual maturities that can be well in excess of ten years. At the end of each reset period, which occurs every seven to twenty-eight days, investors can sell or continue to hold the securities at par. In the first quarter of 2008, certain auction rate securities failed auction due to sell orders exceeding buy orders. We reviewed our portfolio at March 31, 2008, and considered other-than-temporary impairment factors, including the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and our ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery of market value, whether the security has been downgraded by a rating agency, the low probability that we will be unable to collect all amounts due according to the contractual terms of the security, to conclude whether ArQule had an other-than-temporary impairment. After this evaluation, we determined that we had a temporary impairment of \$3.7 million, which we recorded in the quarter ended March 31, 2008 within other comprehensive loss. ArQule's marketable securities portfolio as of December 31, 2007 was \$124.2 million. The portfolio included \$92.6 million (at cost) invested in auction rate securities of which, \$67.7 million (at cost) were associated with auctions that failed subsequent to February 12, 2008. In the quarter ended March 31, 2008, ArQule was able to sell \$26.2 million (at cost) of auction rate securities that were held at December 31, 2007. ArQule's marketable securities portfolio as of March 31, 2008 was \$66.7 million (at cost) invested in auction rate securities all of which were associated with auctions that failed subsequent to February 12, 2008. Subsequent to March 31, 2008, we were notified that certain of our auction rate securities totaling \$1.0 million are planned to be called for redemption and accordingly we expect to receive payment by the end of June 2008. The funds associated with failed auctions will not be accessible until a successful auction occurs, a buyer is found outside of the auction process or the underlying securities have matured.

Estimating the fair value of investments in auction rate securities, requires numerous assumptions such as assessments of the underlying structure of each security, expected cash flows, credit ratings, and other relevant factors. These assumptions, assessments and the interpretations of relevant market data are subject to uncertainties, are difficult to predict and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value. There is no assurance as to when the market for auction rate securities will stabilize. The fair value of our auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. If conditions in the credit markets deteriorate further causing additional auctions to fail, the funds associated with these auction rate securities may also not be accessible for an undetermined period of time, and we may be required to record unrealized losses in other comprehensive income (loss) or an additional impairment on our auction rate securities portfolio in future quarters.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS. None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES. None.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS. None.

ITEM 5. OTHER INFORMATION.

On May 8, 2008, the Company entered into a \$15 million standard margin loan agreement which is secured by the auction rate securities held by the Company. The margin loan currently bears interest at LIBOR plus 25 basis points. As of May 12, 2008, there was no outstanding amount

under this margin loan.

ITEM 6. EXHIBITS

EXHIBIT

NO.	DESCRIPTION
10.1*	Amendment to Employment Agreement, effective as of January 7, 2008, by and between ArQule, Inc. and Stephen A. Hill. Filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on January 8, 2008 (File No. 000-21429) and incorporated by reference herein.
31	Rule 13a-14(a) Certificate of the Principal Executive and Financial Officer, filed herewith.
32	Rule 13a-14(b) Certificate of the Principal Executive and Financial Officer, filed herewith.

* Indicates a management contract or compensatory plan.

ARQULE, INC.

SIGNATURES

Edgar Filing: ARQULE INC - Form 10-Q

Pursuant to the requirements of the Securities Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ArQule, Inc.

Date: May 12, 2008

/s/ PETER S. LAWRENCE
Peter S. Lawrence
President and Chief Operating Officer
(Principal Executive and Financial Officer)

/s/ ROBERT J. WEISKOPF
Robert J. Weiskopf
Vice President of Finance,

Corporate Controller and Treasurer

(Principal Accounting Officer)
